Appln No.: 10/828,394

Amendment Dated: March 28, 2006

Reply to Office Action of February 28, 2006

## **REMARKS/ARGUMENTS**

This is in response to the Office Action mailed February 26, 2006 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claims 1-5 have been canceled without prejudice. Reconsideration of the rejections of Claims 6-8 are respectfully requested.

The Examiner has maintained the rejection of claim 6 as lacking written description. Applicants again traverse this rejection. The Examiner states that this rejection is maintained because "the scope of the instant claims is directed to inhibition of clusterin in all species and thus encompasses things that are not known in the art." Applicants submit that this is an inappropriate standard. The Examiner implies that the known sequences may not be representative, but has not met the burden of showing why they would not be. This fails to meet the Examiner burden of showing why a person skilled in the art would find the disclosure lacking. *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976).

In considering the question of compliance with the written description requirement, it is important to look at the **claimed invention** and not at an individual element. Thus, the question posed should not be whether Applicants have a written description of specific clusterin sequences and inhibitors because applicants are not claiming clusterin sequences and inhibitors per se. They are claiming a method of reducing angiogenesis, and the question with respect to this question must be whether the specification demonstrates a recognition/conception of the invention at this scope.

Applicants respectfully direct the Examiner's attention to several recent cases from the Court of Appeals for the Federal Circuit in which the importance of looking at the claimed invention is demonstrated. *Capon v. Eshhar*, 76 USPQ 2d 1078 (Fed. Cir. 2005) is based on an interference proceeding in which both parties claimed chimeric genes comprising a gene segment encoding a single-chain (scFv) antibody, and a second gene encoding a cytoplasmic signaling domain. Expression of a chimeric gene resulted in cells that expressed a cell surface marker that produced cell signaling in response to binding of an antigen to the scFV antibody. The Board of Patent and Appeals and Interferences had held that both specifications were lacking in written description because of a limited number of examples, and the absence of a complete sequence of at least one chimeric gene within the scope of the claims. In vacating the decision of the Board of Appeals holding, the Federal Circuit observed that "the 'written description' requirement must be applied in the context of the particular invention." 76 USPQ2d at 1084-5. More recently, in *Invitrogen Corp. v. Clontech Laboratories Inc.*, 77 USPQ2d 1161 (Fed. Cir. 2005) upheld a finding on motion for summary judgment that a specification provided adequate written

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description for modified reverse transcriptase (RT) based on a finding of starting sequences in the art in addition to those in the specification.

In *Invitrogen* the claims found to have adequate written description are not limited to RTs where the basic sequence was already known. Similarly, the claims at issue in *Capon* were not limited so as to exclude later developed single chain antibodies or later discovered or characterized signaling domains. Thus, the Examiner's argument is inconsistent with these decisions. Thus, Applicants submit that the written description rejection of claim 6 should be withdrawn.

The Examiner has provisionally rejected claims 6 and 7 for obviousness-type double patenting over claims 20, 21 and 29 of US Patent Application No. 10/646,436. Applicants again traverse this rejection. In assessing obviousness-type double patenting, it is not sufficient to show that a claim in another is generic with respect to the claims of the application under consideration. Rather, the Examiner must show that the subject matter which is under examination is an obvious variant of that which is claimed. In this case, the Examiner has treated now canceled claim 1 and pending claim 6 as if they were identical in scope and has not separately addressed what justifies an assertion that claim 6 is an obvious variant of claim 20. This being the case, the Examiner has failed to present a prima facie case for obviousness-type double patenting. The rejection should therefore be withdrawn.

The Examiner has maintained the rejection of claims 6-8 as anticipated by Monia et al. US 6,383,808 but has not said why this rejection is maintained. The Examiner does acknowledge that "Monia et al. is silent with regard to reduction of angiogenesis," but says that this is not relevant because this "is not required by claims 1 and 2." It is, however, required in claims 6-8, and the Examiner has not said why the rejection of these claims is maintained given this difference. The same is true with respect to the other anticipation rejections.

Anticipation requires the disclosure in the reference of each and every element of the claimed invention. The references relied upon as anticipatory are all silent with respect to angiogenesis. Thus, none of them teaches the invention as claimed in claims 6-8. It is further noted that simply because reduction in angiogenesis **may** have occurred does not give rise to a basis for an anticipation rejection under principles of inherency. *In re Oelrich*, 212 USPQA 323, 326 (CCPA 1981). Thus, the anticipation rejections are in error and should be withdrawn.

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For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

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